

Patent Claims

1. Pharmaceutical preparation of at least two active substances capable of being combined, containing
 - a tiotropium salt as one of the active substances, in a concentration based on tiotropium of between 0.0005 and 5 % by weight;
 - another active substance which is capable of being combined with the tiotropium salt,
 - water or a water/ethanol mixture as solvent for the active substance,
 - acid for achieving a pH between 2.0 and 4.5,
 - a pharmacologically acceptable preservative,
 - optionally a pharmacologically acceptable complexing agent and/or stabiliser and/or a [sic] and/or a pharmacologically acceptable cosolvent and/or other pharmacologically acceptable adjuvants and additives in addition to the preservative.
2. Pharmaceutical preparation according to claim 1, characterised in that the tiotropium salt is a salt with HBr, HCl, HI, monomethylsulphuric acid ester, methanesulphonic acid and/or p-toluenesulphonic acid.
3. Pharmaceutical preparation according to claim 1, characterised in that the active substance is tiotropium bromide.
4. Pharmaceutical preparation according to claim 1, characterised in that the active substance is tiotropium bromide monohydrate.

5. Pharmaceutical preparation according to one of claims 1 to 4, characterised in that the solvent is water.
6. Pharmaceutical preparation according to one of claims 1 to 4, characterised in that the solvent is a water-ethanol mixture with preferably up to 70 vol.% of ethanol, more preferably up to 60 vol.% of ethanol and most preferably up to 30 vol.% of ethanol.
7. Pharmaceutical preparation according to one of claims 1 to 6, characterised in that it does not contain a complexing agent.
8. Pharmaceutical preparation according to one of claims 1 to 7, characterised in that it does not contain a stabiliser.
9. Pharmaceutical preparation according to one of claims 1 to 6, characterised in that editic acid salt is present in an amount of greater than 0 up to 25 mg /100 ml, preferably from 5 to less than 10 mg /100 ml.
10. Pharmaceutical preparation according to claim 9, characterised in that the editic acid salt is sodium edetate.
11. Pharmaceutical preparation according to one of claims 1 to 10, characterised in that the pH is between 2.5 and 3.5, preferably between 2.7 and 3.3 and most preferably between 2.7 and 3.0.
12. Pharmaceutical preparation according to one of claims 1 to 11, characterised in that the concentration of tiotropium is between 0.0005 and 5 % by weight, preferably up to 3% by weight.
13. Pharmaceutical preparation according to one of claims 1 to 12, characterised in that the preparation contains benzalkonium chloride as preservative.

14. Pharmaceutical preparation according to one of claims 1 to 6 and 9 to 13, characterised in that cosolvents and/or pharmacologically acceptable adjuvants and additives are used in addition to the preservative.
15. Pharmaceutical preparation according to claim 14, characterised in that the preparation contains an antioxidant as adjuvant.
16. Pharmaceutical preparation according to one of claims 1 to 15, characterised in that no cosolvents and/or pharmacologically acceptable adjuvants and additives are used apart from the preservative.
17. Pharmaceutical preparation according to one of claims 1 to 15, characterised in that the preparation contains another active substance or a plurality of other active substances selected from among the betasympathomimetics, antiallergics and/or antihistamines.
18. Pharmaceutical preparation according to claim 17, characterised in that the concentration of tiotropium is between 0.001 and 3 % by weight, preferably 0.0005 to 0.5 % by weight, more preferably 0.0005 to 0.25 % by weight and particularly preferably 0.001 to 0.1 % by weight.
19. Pharmaceutical preparation according to claim 18, characterised in that the additional active substance is salbutamol, salbutamol sulphate, formoterol, formoterol hydrobromide, budesonide and/or flunisolide.
20. Pharmaceutical preparation containing water, 0.1 % by weight of tiotropium bromide, another active substance capable of being combined with tiotropium, 0.01 % by weight of benzalkonium chloride, 0.05 % by weight of sodium edetate, which is adjusted to a pH of 3.0 using hydrochloric acid.
21. Pharmaceutical preparation according to one of claims 1 to 20 for use as a pharmaceutical composition for administration by inhalation.

22. Use of a pharmaceutical preparation according to one of claims 1 to 21 for nebulising in an inhaler according to WO 91/14468 or an inhaler as described in Figures 6a and 6b of WO 97/12687.
23. Use of a pharmaceutical preparation according to one of claims 1 to 21 for nebulising in an inhaler which nebulises defined amounts of the pharmaceutical formulation by the application of pressures from 100 to 600 bar through a nozzle having at least one nozzle opening with a depth of 2 to 10 microns and a width of 5 to 15 microns to form an inhalable aerosol.
24. Use according to claim 23, characterised in that the at least one nozzle opening is at least two nozzle openings which are inclined relative to one another in the direction of the nozzle opening at an angle of from 20 degrees to 160 degrees.
25. Use according to claim 20 or 21, characterised in that the defined amounts are 10 to 50 microlitres.
26. Use according to one of claims 22 to 25, characterised in that the inhaler is 9 to 15 cm long and 2 to 4 cm wide.
27. Use according to one of claims 22 to 26, characterised in that the mass of formulation delivered in at least 97% of all actuations of the inhaler is between 5 and 30 mg with a range of tolerance of 25%.
28. Use according to one of claims 22 to 26, characterised in that the mass of formulation delivered in at least 97% of all actuations of the inhaler is between 5 and 30 mg with a range of tolerance of 20%.
29. Use according to one of claims 27 or 28, characterised in that the mass delivered is achieved in at least 98% of all actuations of the inhaler.